TABLE 22.—PRESENT VALUES FOR SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 6 (PROPOSED OPTION)

Test	Present Value of Base Total Cost	Present Value of New Total Cost Under Test Assumption	Change in Present Value
50% prior notices changed	$5,258,695,269	$6,355,779,211	$1,097,083,942
15% prior notices change with amendment	$957,198,397	$1,130,875,983	$173,677,586
5% lost value for produce, 12% lost value for seafood	$957,198,397	$1,177,557,426	$220,359,029
Retail value is 200% of wholesale value	$957,198,397	$1,000,617,783	$43,419,386
Prior notice entries increase 3% in second year	$957,198,397	$985,384,983	$28,186,586
3% Discount rate	$957,198,397	$2,209,935,673	$1,252,737,276

Benefits: Requiring prior notice of imported food shipments and defining the required data elements should improve FDA's ability to detect accidental and deliberate contamination of food and deter deliberate contamination. Having notice of an imported food shipment before it reaches a U.S. border would allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry represents a serious threat to human or animal health.

Historical evidence suggests that a terrorist or other intentional strike on the food supply is a low-probability, but potentially high-cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring, or the possible reduction in cost of an event associated with each regulatory option. Further hindering any quantification of benefits are the complementary effects of the other regulations that are being developed to implement Title III of the Bioterrorism Act.

To understand possible costs of an intentional strike on the food supply, FDA examined five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. An intentional

attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens could be much larger than the examples given.

TABLE 23.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
Salmonella enteritidis	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN 224,00 Nationwide	$3,187,744,000 to $5,629,792,000
Shigella sonnei	Michigan, 1988	Tofu salad	3,175 cases	Not available	$45,183,000 to $79,795,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalizations	Not available	$10,687,000 to $18,875,000
Shigella dysentreriae type 2	Texas, 1996	Muffins and doughnuts	12 cases; 4 hospitalizations	All cases identified	$83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalization	Not available	$3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with Salmonella enteritidis. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that previously had carried non-pasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref 11).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as requiring a trip to a physician, account for 8 percent of the cases. These cases typically have duration of two to 12 days. Severe cases require

hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over one percent of cases develop short-term reactive arthritis and two percent of cases develop chronic, reactive arthritis.

In table 17, FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a Quality Adjusted Life Year (QALY), or the loss of a year of life is valued at $100,000, based on economic studies of how consumers value risks to life (Ref 12). Thus, an entire lost QALD would be valued at $274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref 13) and another based on a regression analysis approach (Ref 14). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

TABLE 24.—THE COST OF AN AVERAGE CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$660	$0	$599
Moderate	8.1%	3.68	$2,310	$283	$209
Severe	1.2%	9.99	$6,266	$9,250	$188
Arthritis					
Regression Approach					
Short-Term	1.26%	5.41	$3,391	$100	$44
Long-Term	2.40%	2,613.12	$452,554	$7,322	$11,048
Direct Survey Approach					
Short-Term	1.26%	10.81	$6,778	$100 $87	
Long-Term	2.40%	5,223.15	$904,573	$7,322	$21,906
Death	0.04%		$5,000,000		$2,143
Total Expected Loss per Case				Regression Approach	$14,231
				Direct Survey Approach	$25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival. (Ref 15) Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus, FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of Salmonella typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying Salmonella typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref 16).

The 751 people affected primarily were identified through passive surveillance: thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates

of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis in Texas in 1996. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 17).

To estimate the cost of this outbreak, FDA assumed that the eight cases that required consultation with a doctor, but did not require hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $82,808 for illnesses associated with the event.

TABLE 25.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of cases	Cost per case	Total cost
Mild	0	$0	$0
Moderate	8	$2,593	$20,744
Severe	4	$15,516	$62,064
Total	12		$82,808

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these

cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref 18). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref 19).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref 20). We estimated the cost of a mild case of cyclosporiasis as two and one half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak. No deaths were confirmed.

TABLE 26.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case	Total cost
Mild	879	$1,650	$1,450,000
Moderate	586	$3,748	$2,196,000
Severe	19	$15,516	$294,000
Total	1,465		$3,941,000

B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. §§ 601–612). If a rule has

a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. The analysis below, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

Number of establishments affected

FDA finds that this proposed rule would affect the 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small businesses according to the definitions of the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A above are regulatory relief options.

Costs per entity

Small businesses will be affected by this proposed rule in a couple of ways. First, this proposed rule requires importers to notify FDA of incoming products electronically before the food arrives at the U.S. border. The annual cost of doing so is about $770 per importer (see tables 1, 2, and 20 ~~above~~ of this document). As discussed above and shown in Tables 1 and 2, about 3,100 U.S. importers do not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about $2,000 per importer) and Internet access (at a cost of about $240 annually) in order to comply with this proposed rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, as paper notices could not be submitted and processed in the proposed prior notice timeframe and would therefore actually be more

burdensome to importers because paper notices would need to be submitted earlier.

Second, this proposed rule will potentially cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before crossing the U.S. border. The costs of lost product value vary with the required notice timeframe. We discuss the various costs associated with this possibility in the options previously outlined ~~above~~. FDA requests comments on the effect of this proposed rule on small entities.

Additional flexibility considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act established a deadline for beginning prior notice that applies to all FDA-regulated imported food. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the prior notice provision contains no such language. Thus, it appears that Congress intended for all entities to be subject to the effective date established in the Bioterrorism Act. Nonetheless, the agency recognizes that the prior notice requirement will cause an economic burden on small businesses; therefore, we are seeking comment on whether it would be consistent with section 307 for the agency to set staggered effective dates that would give small businesses more time to comply. FDA also seeks comment

on how FDA could effectively distinguish between large and small businesses if it considered staggered effective dates.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $112 million. FDA has determined that this proposed rule does constitute a significant rule under the Unfunded Mandates Reform Act. See table 20 for the total costs.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prior Notice of Imported Food

Description: Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 381(m)) requires prior notification to the Secretary of Health and Human Services of an article of food that is being imported or offered for import into the United States. The purpose of this notification is to enable the food to be inspected at ports of entry into the United States.

Section 801(m) of the Act states that the Secretary shall by regulation identify the parties responsible for providing the notice and explain the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 801(m)(1) of the Act states that the Secretary shall require submission of notice providing the identity of each of the following: the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. Section 801(m)(2)(A) of the Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. FDA's prior notification of imported food shipments proposed regulation would implement these statutory provisions.

FDA estimates the burden for this information collection as follows:

TABLE 20.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, Subpart I	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.285–1.290, 1.294[1]	77,427	23.3	1,807,692	1–2	$6,194,000	$743,280	1,888,216
1.278(d)[1]	90,385	1	90,385	0.5	$0	$0	45,193
1.278(d), 1.285–1.290, 1.294[2] Total hours for first year Total recurring hours	77,427	23.8	1,844,116	0.5–1	$620,000	$817,680	1,833,822 1,833,216 1,833,822

[1] First year burden.
[2] Recurring burden.

Burden Estimate:

Number of establishments affected:

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52,54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food for human and animal consumption into the United States. It is these 77,427 U.S. importers or U.S. purchasers (or their agents) that will be primarily responsible for submitting the prior notice information.

New and closing importers

In addition to the U.S. importers currently in existence, in future years, new import businesses will open and some existing import businesses will close. These new importers would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about ten percent of all businesses were new and ten percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA will assume,

then, that on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

Hour Burden Estimate Researching the prior notice requirement

To become familiar with the requirements for this rule, FDA estimates it will initially take responsible parties with Internet access (74,330 importers) about one hour to research the prior notice requirements and responsible parties without readily available Internet access (3,097 importers) about 2 hours to research the requirements. This one-time search burden for the existing importers is 80,524 hours.

In the years that follow the start-up year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. Thus, in addition to the first year burden to research prior notice, it is expected that 8,053 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

Submitting prior notice

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this

number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

Secure storage and notifying FDA

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter. This means that of the 1,807,692 prior notice entries received annually, in the first year prior notice is in effect we would expect 90,385 of the entries to be held or sent to secure storage; 36,154 entries would be held or sent to secure storage in subsequent years.

Most port storage facilities and secure storage facilities located at or near ports are probably familiar to submitters or carriers; therefore it should only take one-half hour per entry to notify FDA of the shipment's location. Thus, in the first year of the regulation, submitters or carriers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we will assume that the 3,097 responsible parties without Internet access will have to purchase the appropriate IT equipment and gain Internet access to actually transmit the

information. Assuming computer equipment costs each firm $2,000 and yearly Internet access costs each firm $240 ($20 per month for 12 months), this results in a one-time computer cost for these facilities of $6,194,000 and a recurring Internet access cost of $743,280. For the 7,743 new firms that enter the import market each year, we can expect 310 of them to need to purchase computer equipment and obtain Internet access. Thus, on an annual basis we can expect new importers to spend $620,000 on computers and $74,400 on Internet access to be able to submit prior notice information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection (see **ADDRESSES**).

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed

rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

VIII. Comments

Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. ~~notice by [*insert date 60 days after date of publication in the* **Federal Register**]. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy.~~ Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary

protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 307 of the Act requires the FDA to propose and issue final regulations requiring prior notice of food imported or offered for import into the United States within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 307 also provides that if FDA does not issue final regulations by this date, FDA still must receive prior notice of food imported or offered for import into the U.S. by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies and FDA's need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the

Website address, but FDA is not responsible for any subsequent changes to the nonFDA Websites after this document publishes in the **Federal Register**.)

1. Compilation of food entry documents, with corresponding invoices and screens, taken from FDA's Operational and Administrative System for Import Support (OASIS).

2. Bureau of Economic Analysis, http://www.bea.doc.gov

3. United States Department of Labor, Bureau of Labor Statistics. National Compensation Survey: Occupation Wages in the United States, 2000. Summary 01–04. Available at http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf.

4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. www.ams.usda.gov

5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, www.thepacker.com/rbcs/handbookarticles/properis.htm Accessed on 9.16.02.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. www.ams.usda.gov

7. Florida Department of Agriculture and Consumer Services (FDACS) www.ffva.com/rps.htm.

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, www.st.nmfs.gov accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, http://doacs.state.fl.us/press/1999/090999.html and www.ffva.com/rps.htm

10. Center for Food Safety and Applied Nutrition, http://www.cfsan.fda.gov/~dms/qa-sto8.html

11. Hennessy TW, Hedberg CW, Slutsker L, White KE, Besser-Wiek JM, Moen ME, Feldman J, Coleman WW, Edmonson LM, MacDonald KL, Osterholm MT, and

the Investigation Team. A National Outbreak of Salmonella enteritidis infections from ice cream. The New England Journal of Medicine. May 16, 1996. 1281–1286.

12. Cutler, D., Richardson, E., 1999. Your Money and Your Life: The Value of Health and What Affects It. Working Paper 6895. National Bureau of Economic Research.

13. Zorn, D., Klontz, K., 1998. Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis", **Federal Register**, 63, May 1, 1998.

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17. Kolavic SA, Kimura A, Simons SL, Slusker L, Barth S, and CE Haley. An outbreak of Shigella dysenteriae type 2 among laboratory workers due to intentional food contamination. JAMA, The Journal of the American Medical Association. 278:5:396–403.

18. Colley DG. Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter). Emerging Infectious Diseases. 2:4:354–356.

19. Herwaldt BL, Ackers ML, and Cyclospora Working Group. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. New England Journal of Medicine. May 29, 1997. 1548–1556.

20. Small Business Administration Office of Advocacy, "Small Business by the Numbers", May 2002, http://www.sba.gov/advo/

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 ~~is revised~~ continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. New subpart I is added to part 1 to read as follows:

registration w/ publish list so prior notice should read continues

Subparts F-G [Reserved]
Subpart I—PRIOR NOTICE OF IMPORTED FOOD
General Provisions

Sec.

Requirements to Submit Prior Notice of Imported Food

Sec.

General Provisions

§ 1.276 *What imported food is subject to this subpart*?

(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.277 *What definitions apply to this subpart?*

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the country of origin is the country in which it is grown and

harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the country of origin is the United States. Otherwise, the country of origin is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

§ 1.278 *What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?*

(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice, the food shall be refused admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) The article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under

section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

Requirements to Submit Prior Notice of Imported Food

§ 1.285 *Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?*

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 *When must the prior notice be submitted to FDA*?

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in § § 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 *How must you submit the prior notice*?

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System, which is available at www.fda.gov/__, except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

§ 1.288 *What information must be submitted in the prior notice*?

For each article of food that is imported or offered for import into the United States, you must submit the information listed below:

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food

under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H, for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;

(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate; and

(r) The identification of the final mode of transport to the United States, i.e., water, air, or land.

(s) The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.

§ 1.289 *What changes are allowed to a prior notice after it has been submitted to FDA*?

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 *Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA*?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for "fresh peppers, refrigerated," when you amend your submission, you must give the product code that identifies with specificity the type of pepper - "fresh green bell peppers, refrigerated." You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for "refrigerated fresh fish" may be amended as "refrigerated fresh cod" and "refrigerated fresh salmon," but not "refrigerated fresh cod" and "canned shrimp." You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 *What is the deadline for product identity amendments under § 1.290?*

Your product identity amendment must be submitted no later than:

(a) 4 hours prior to the time of arrival if the final mode of transport to the United States is by water; or

(b) 3 hours prior to the time of arrival if the final mode of transport to the United States is by air; or

(c) 2 hours prior to the time of arrival if the final mode of transport to the United States is by land.

§ 1.292 *How do you submit a product identity amendment to a prior notice?*

You must submit product identity amendments in accordance with § 1.287.

§ 1.293 *What are the consequences if you do not submit a product identity amendment to your prior notice?*

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 *What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?*

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

(c) You must update the information in accordance with the requirements of § § 1.291 and 1.292.

(d) If you do not submit an arrival update when one is required by paragraph (a) of this section, the prior notice is inadequate for the purposes of § 1.278(a).

Dated: _____

_____

Dated: _____

_____

form is an — that

Note: The following appendix will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PRIOR NOTICE SUBMISSION

Form Approved: OMB No. 0910-____
Expiration Date: _____

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 0.5-1.0 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office to be Determined
5100 Paint Branch Parkway
College Park, MD 20740-3835

☐ Initial	☐ Held	☐ Amendment Product Identity	☐ Update Arrival Info	☐ Cancel

Mandatory Information	Mandatory if applicable

Submitter

First Name	
Last Name	

Submitting Firm

☐ U.S. Purchaser	☐ U.S. Importer
☐ U.S. Agent of Purchaser	☐ U.S. Agent of Importer
☐ Carrier	☐ In-bond Carrier

Name of Firm		
FDA Registration Number	☐ N/A	#
Street Address		
City		
State		
Zip		
Phone		
FAX		
E-mail address		

Entry Type

☐ Consumption	☐ T & E	☐ IE	☐ Mail	☐ Trade Fair
☐ Warehouse	☐ TIB		☐ Baggage	☐ Other

Entry Type Customs Code

Customs Entry Number/Customs Line Number/FDA Line Number

Article held under FDA direction	☐ No	☐ Yes	
Name of Location			
Street Address			
City			
State		Zip	
Contact Name		Phone	

Date available at Location mm/dd/yy							

Product Identity

FDA Product Code							

Common/usual/market name	
Trade/brand name	

Quantity	Number	Measure

Identifiers	□ Lot number	□ Production Code
1		
2		
3		
4		

Manufacturer

Name of Firm		
FDA Registration Number	□ N/A	#
Street Address		
City		
State/Province		
Country		
Zip/Mail code		
Phone		
FAX		
E-mail address		

Grower

Name of Firm		
Street Address		
City		
State/Province		
Country		
Zip/Mail code		
Phone		
FAX		
E-mail address		
Growing Location street		
Growing Location City		
Growing Location State/Province		
Growing Location Country		
Growing Location Zip/Mail code		
ADDITIONAL GROWERS	□ No □ Yes	How Many?

GROWER 2

Name of Firm		
Street Address		
City		

State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Growing Location street	
Growing Location City	
Growing Location State/Province	
Growing Location Country	
Growing Location Zip/Mail code	
GROWER 3	
Name of Firm	
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Growing Location street	
Growing Location City	
Growing Location State/Province	
Growing Location Country	
Growing Location Zip/Mail code	
Originating Country	ISO code
Shipper	
Name of Firm	
FDA Registration Number	☐ N/A #
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Country from which the article was shipped	ISO code
Anticipated Arrival Information	
Name of Crossing	

City of Crossing	
State of Crossing	Port of Entry Code
Anticipated Date of Crossing mm/dd/yy	
Anticipated Time of Crossing	☐ am ☐ pm
Port of Entry for Customs Purposes (port code)	
Date of Entry for Customs Purposes mm/dd/yy	

Importer	
Name of Firm	
FDA Registration Number	☐ N/A #
Street Address	
City	
State	
Zip	
Phone	
FAX	
E-mail address	

Owner	
Name of Firm	
FDA Registration Number	☐ N/A #
Street Address	
City	
State	
Zip	
Phone	
FAX	
E-mail address	

Consignee	
Name of Firm	
FDA Registration Number	☐ N/A #
Street Address	
City	
State	
Zip	
Phone	
FAX	
E-mail address	

Carrier 1	
Standard Carrier Abbreviation Code	
Name of Firm	
Street Address	

City				
State/Province				
Zip/mail code				
Country				
Phone				
FAX				
E-mail address				
Additional Carriers	☐ No	☐ Yes	How Many?	
Carrier 2				
Standard Carrier Abbreviation Code				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
Carrier 3				
Standard Carrier Abbreviation Code				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
Mode of Transport				
LAND	☐ Truck	☐ Auto	☐ Other	
AIR	☐ Plane	☐ Other		
WATER	☐ Boat	☐ Ocean vessel	☐ Other	
Amendment to follow		☐ Yes	☐ No	
Cancel this submission		☐ Yes	☐ No	

This form must be submitted by the U.S. Importer or U.S. Purchaser, or U.S. Agent of the importer or purchaser, of the article of food being imported or offered for import. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

OMB 1/22/03